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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/991,001	11/14/2001	Michael L. Bell	1840-045	4728

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EXAMINER

HAQ, SHAFIQL

ART UNIT PAPER NUMBER

1641

DATE MAILED: 10/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/991,001

Applicant(s)

BELL ET AL.

Examiner

Shafiqul Haq

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-11 and 13-28 is/are pending in the application.
- 4a) Of the above claim(s) 2-6, 8-11 and 22-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 7 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Status of Claims

1. Applicants' responses and amendments filed on December 14, 2005 is acknowledged and entered.
2. Claims 2-11 and 13-28 are pending. Claims 4, 13-21 and 24-28 are withdrawn by Applicants as being directed to non-elected species. Amended claims 6, 8, 9, 10, 11 and 22-23 contain non-elected ion sensors (nucleotide sequence-sensor or enzyme-sensor or both) as required component of the reagent. and therefore, are withdrawn form further consideration as being as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. Therefore, claims 2-6, 8-11 and 22-28 are withdrawn form further consideration as being as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.
3. Claim 7 is examined on merits.

Response to Election/Restriction

4. Restriction/election requirement were made FINAL in office action of 6/14/05 and the reason for election and restriction were also described. Applicants' requested to consider non-elected species of claim 22 as additional species in the event the elected species is found allowable. Applicants' argument is persuasive and therefore, in the event claim 7 (comprising elected species ion-sensor, metabolite-sensor and antigen-antibody sensor) is allowable, claims 9, 11 and 22 with enzyme-sensor or nucleotide sensor or both as additional species would be considered.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over McDevitt et al (US 6,680,206 B1) in view of Engh et al (US 5,747,349).

McDevitt et al. disclose plurality of sensitive particles (sensor particles) for identification of multiple analytes in a sample (see title and abstract and column 4, lines 35-49 and claims 2-3). The particles may include various receptor molecules such as DNA (nucleic acid sensor), enzymes (enzyme sensors), antigens and antibodies (antigen-antibody sensor) to bind analyte of interest (column 5, lines 35-49; column 15, lines 63-67 and column 16, lines 1-12; column 20, lines 31-35, 54-57 and claims 20, 27-33) and to create a modulated signals (e.g. fluorescence) (column 15, lines column 18, lines 22-24, 66-67; column 19, lines 1-31 and claims 25, 26 and 36). The reagent also comprises ion sensor particles (e.g. for detection of pH, alkaline earth metal ions such as Ca^{+2}) (column 17, lines 31-45; examples 1, 2 and claims 22-23) and metabolite sensor particles (e.g. for detection of saccharides) (column 6, lines 14-19 and claim 24) that interact with specific ions or metabolite to emit detected signals (e.g. fluorescence) (column 19, lines 9-31; column 24, lines 23-26, lines 56-61 and column 26, lines 17-23).

McDevitt et al. disclose plurality of sensitive particles arranged in an array format but fail to disclose different classes of sensor particles as mixture in a fluid.

Van den Engh et al. disclose mixture of reagents in a fluid comprising different reporter beads (sensor particles: e.g. ion sensor particles, metabolite sensor particles) for assaying multiple analytes in a sample (see abstract). Van den Engh et al. disclose that ion sensor particles interact specifically with analyte selected from group consisting of alkali metal ions (column 3, line 8) and metabolite sensor particles interact specifically with analyte selected from group consisting of saccharide such as glucose (column 3, lines 10-11). The reference further disclose antigen-antibody coated fluorescent beads (antigen-antibody sensor particles) in the background (column 1, lines 50-67) and disclose that beads tagged with different reporter molecules (sensor particles) can be mixed with one sample and plurality of analytes can be measured simultaneously (column 2, lines 40-42).

Van den Engh et al. also disclose several advantages of using mixture of different reporter beads in a fluid. One advantage is that the measurement does not require incubation, washing, or filtration steps; reporter beads can be mixed with a fluid sample and the fluorescence measured without further processing. Other advantage is that beads tagged with different reporter molecules can be mixed within one sample and a plurality of analytes can be measured simultaneously.

Therefore, given the above advantage of using mixture of reporter beads in a fluid for detection of multiple analytes, it would have been obvious at the time of the invention to a person of ordinary skill in the art to use plurality of sensor particles of

McDevitt et al. in a mixture format as taught by Van den Engh to detect multiple analytes in a sample efficiently with less manipulation, with a reasonable expectation of success because Van den Engh et al. teach common reaction environment for analyzing multiple analytes in a mixture.

Response to Argument

7. Applicant's arguments and amendments filed December 14, 2005 have been fully considered, and are persuasive to overcome the rejections under 35 USC 112 and 35 USC 102 but the references are still applicable for rejection under 35 USC 103(a) as described in paragraph 6 of this office action.

35 U.S.C. §103 rejection is based on obviousness, not on anticipation and obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fines*, 837 F.2d 1071, 5USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir.1992). In this case, McDevitt et al. disclose plurality of sensitive particles (sensor particles) for identification of multiple analytes in a sample in an array format and Van den Engh et al. disclose plurality of sensitive particles (sensor particles) for identification of multiple analytes in a mixture format and disclose several advantages of using mixture of different reporter beads (i.e. plurality of sensor particles) in a fluid for analysis of multiple analytes in a sample. Since both McDevitt and Van den Engh are concerned with the same problem i.e. analysis of multiple

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analytes using plurality of sensitive particles (sensor particles) and Van den Engh discloses several advantages for carrying out analysis in a fluid mixture, one of ordinary skill in the art would be motivated to modify McDevitt with the teaching of Van den Engh.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shafiqul Haq whose telephone number is 571-272-6103. The examiner can normally be reached on 7:30AM-4:00PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



SHAFIQUL HAQ
EXAMINER
ART UNIT 1641



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